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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,536	12/28/2004	Yoshikatsu Kodama	2004_2037A	2533

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/519,536	KODAMA ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/28/04, 4/11/05, 12/05/05, 3/06/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are pending and under examination.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in Application No. 10/519,536, filed on June 28, 2002. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 12/28/04, 4/11/05 and 12/05/05 are in compliance with the provisions of 37 CFR 1.97 and have been considered by the examiner. However, The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The disclosure is objected to because of the following informalities: The word "sporozoit" is misspelled throughout the entire specification and should be spelled sporozoite.

Appropriate correction is required.

Claim Objections

4. Claim 1 is objected to because of the following informalities: The word "sporozoit" is misspelled and should be spelled sporozoite.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating chicken coccidiosis wherein the antibody is obtained from an egg of a chicken immunized with an antigenic outer membrane protein or an immunogenic fragment thereof having a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella,* and *Eimeria maxima* and is orally administered to a bird optionally in combination with a lactic acid bacterium and/or an antibody obtained from an egg of a

chicken immunized with *Clostridium perfringens*, does not reasonably provide enablement for a method for preventing chicken coccidiosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A vaccine must by definition provide an immunoprotective response upon administration. The specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity against chicken coccidiosis. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing coccidiosis. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced. The instant specification speaks to the treatment of chicken coccidiosis by way of increasing the average weight gain, food intake and decreasing the oocyst score etc. Applicant submits that the claimed composition is considerably effective and the above-mentioned factors are significantly improved (page 15, 2nd ¶ and table 1). The examiner has not seen an example in the specification where a pathogen free bird was administered the claimed composition and as a result the bird was protected from coccidiosis. Was the above-mentioned composition ever administered to a subject that was not infected with coccidiosis prior to the administration of the claimed composition? Where is the data showing the resulting protection?

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is s induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

Wallach et al (Passive immunization of chickens against *Eimeria maxima* infection with a monoclonal antibody developed against a gametocyte antigen, Infection and Immunity, 1990; 58(2): 557-62) discloses that the antigenic diversity of *E. maxima* is considered to be a major problem in the development of a vaccine against this species. This is based on the finding that an infection with one strain of *E. maxima* does not protect against challenge with a different strain (page 561, 2nd column).

Moreover, Dalloul et al (Poultry coccidiosois: recent advancements in control measures and vaccine development, Expert Rev. Vaccines, 2006; 5(1): 143-163) discloses that increasing evidence shows the magnitude of complexity involved in host immune responses to Eimeria. Additional basic research is needed to ascertain the detailed immunologic and physiologic processes mediating protective immunity. Lastly

Dalloul et al discloses that critical resources are severely lacking, which make is difficult to fulfill timely progress (page 156, concluding remarks).

The Wands factors have been considered in the establishment of this scope of enablement rejection:

a. the quantity of experimentation necessary would be undue for the prevention of coccidiosis;

b. the amount of direction or guidance has not been presented;

c. the presence or absence of working examples displaying the protection/prevention of chicken coccidiosis has not been provided;

d. the nature of the invention is one that without specific guidance would be problematic;

e. the state of the prior art is one which states that additional basic research is needed to ascertain the detailed immunologic and physiologic processes mediating protective immunity;

f. the relative skill of those in the art: high;

g. the predictability or unpredictability of the art: unpredictable because critical resources are severely lacking making it difficult to fulfill timely progress ; and

h. breadth of the claims: broad.

Since the immune response is considered to be one of the most complex and unpredictable biological processes and in view of the prior art teachings and all of the

above, it is determined that it would require undue experimentation to use the claimed composition for preventing chicken coccidiosis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

In light of the priority notice cited above the following rejections are based upon the filing date of the Japanese application (06/28/02) which has not been translated.

6. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds (US 5,807,551).

Claims 1 and 3-5 are drawn to an anti-chicken coccidiosis composition for oral administration comprising an antibody obtained from an egg of a chicken immunized with an antigenic outer membrane protein or an immunogenic fragment thereof having a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella,* and *Eimeria maxima* which are associated with chicken coccidiosis.

Reynolds discloses an anti-chicken coccidiosis composition where antibodies are obtained from birds immunized with Eimeria spp. (column 4, lines 5-13). Reynolds

discloses that the antibodies are collected from the egg yolk and harvested (column 4, lines 19-20). The antibodies are then resuspended into a composition and are administered to the bird (column 4, lines 42 and 65-66).

Claim limitations such as "an avian feed" and "for oral administration" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. an immunogenic composition and a vaccine comprising an antibody. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically

significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Therefore the process limitation is met by the teachings of the prior art.

7. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Garzon et al (US 2006/0024294 A1).

Claims 1 and 3-5 are drawn to an anti-chicken coccidiosis composition for oral administration comprising an antibody obtained from an egg of a chicken immunized with an antigenic outer membrane protein or an immunogenic fragment thereof having a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella,* and *Eimeria maxima* which are associated with chicken coccidiosis.

Garzon et al discloses anticoccidial compostions. The compositions, which can be administered orally, contain immunoglobulins extracted from the yolks of eggs (0019, 0021). Garzon et al discloses that the antigen to be administered to the hen could be a parasite in any stage of it life cycle, including oocyst, sporozoites, merozoites or whole parasites from the family of Eimeria consisting of *E. tenella, E. acervulina, E. maxima, E. necatrix, E. brunette, E. mitis, E. praecox* or *E. hagani* (0024). Once the eggs from the immunized hen show anticoccidial immunoglobulins the eggs are collected and the

anticoccidial composition is made (0029-33). Lastly, Garzon et al discloses that the composition is suitable for oral administration through drinking water or mixed with food (0012).

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. an immunogenic composition and a vaccine comprising an antibody. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Therefore the process limitation is met by the teachings of the prior art.

8. Claim 6 is rejected under 35 U.S.C. 102(e) as being anticipated by Garzon et al (US 2006/0024294 A1).

Claim 6 is drawn to a method for preventing or treating chicken coccidiosis wherein the antibody of claim 1 is orally administered to a bird optionally in combination with a lactic acid bacterium and/or an antibody obtained from an egg of a chicken immunized with *Clostridium perfringens*.

Garzon et al discloses a method for the prevention and treatment of chicken coccidiosis by orally administering an anticoccidial composition, which contain immunoglobulins extracted from the yolks of eggs (0019, 0021). Garzon et al discloses that the antigen to be administered to the hen could be a parasite in any stage of life cycle, including oocyst, sporozoites, merozoites or whole parasites from the family of Eimeria consisting of *E. tenella, E. acervulina, E. maxima, E. necatrix, E. brunette, E. mitis, E. praecox* or *E. hagani* (0024). Once the eggs from the immunized hen show anticoccidial immunoglobulins the eggs are collected and the anticoccidial composition is made (0029-33).

The limitation of "optionally in combination with a lactic acid bacterium and/or an antibody obtained from an egg of a chicken immunized with *Clostridium perfringens*" is being viewed as a limitation that does not have to be present.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art.

See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds (US 5,807,551) as applied to claims 1 and 3-5 above, and further in view of (Garzon et al (US 2006/0024294 A1).

Claim 6 is drawn to a method for preventing or treating chicken coccidiosis wherein the antibody of claim 1 is orally administered to a bird optionally in combination with a lactic acid bacterium and/or an antibody obtained from an egg of a chicken immunized with *Clostridium perfringens.*

Reynolds discloses the limitations of claims 1 and 3-5 above. Reynolds does not teach a composition for oral administration.

Garzon et al discloses a method for the prevention and treatment of chicken coccidiosis by orally administering an anticoccidial composition, which contain immunoglobulins extracted from the yolks of eggs (0019, 0021).

Reynolds and Garzon et al disclose analogous inventions related to methods for preventing and treating chicken coccidiosis wherein the antibody is extracted from the

yolk of eggs. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Reynolds with the teachings of Garzon et al to more effectively decrease mortality, lesions, oocysts counts and increase the weight gain of the receiving animals. It would have been expected, barring evidence to the contrary, that the method would be effective in preventing or treating chicken coccidiosis.

Conclusion

10. No claims are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ivey et al (US 2004/0052895 A1)

Brown et al (US 6,019,985)

Davelaar (US 6,998, 126 B2)

Smith et al (Maternal transfer of antibodies induced by infection with *Eimeria maxima* partially protects chickens against challenge with *Eimeria tenella,* Parasitiology, 1994; 109: 551-57).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT
3/29/06

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600